(27)

No. 95-728

IN THE
Supreme Court of the United States
OCTOBER TERM, 1995

WARNER-JENKINSON COMPANY, INC.,
Petitioner,

v.

HILTON DAVIS CHEMICAL CO.,
Respondent.

On Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

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REPLY BRIEF FOR PETITIONER

H. BARTOW FARR, III
(Counsel of Record)
RICHARD G. TARANTO
FARR & TARANTO
2445 M Street, NW
Washington, DC 20037
(202) 775-0184

J. ROBERT CHAMBERS
KURT L. GROSSMAN
WOOD, HERRON & EVANS
2700 Carew Tower
Cincinnati, OH 45202

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REPLY BRIEF FOR PETITIONER

The Patent Act's cause of action for infringement protects against unauthorized use of the patentee's "invention." 35 U.S.C. § 271(a). The question in this case is how the scope of the "invention" is to be determined. Our position is that the invention protected by the federal patent monopoly cannot go beyond what the patentee has told the PTO (and hence the public) its invention is. Whether limited to the *claim* portion of the patent (fairly read in full context), or permitted to point to the whole patent and its documented history for clearly disclosed equivalents of claim elements, the patentee may not in an infringement suit invoke as its invention something not asserted as the invention before the PTO. This view reflects the statute's central principles that it is up to the patentee, in its disclosures made to and approved by the expert agency, to define the invention for which the federal monopoly is granted [1]; that the public is entitled to rely on a reading of those disclosures, and not undertake independent scientific experiments, to understand clearly the scope of the monopoly [2]; and that the basic "bargain

[1] *See, e.g.*, 35 U.S.C. § 112 (patent applicant must "distinctly claim[]" what he "regards as his invention"); *id.* § 131 (if "the alleged new invention" meets statutory requirements, the PTO must "issue a patent therefor"); Pet. Br. 14-15. *See also* Chiron Br. 12 n.5 ("The Act *defines* 'invention' through section 112, which states that an applicant must claim 'the subject matter which the applicant regards as his invention.'" (emphasis added)).

[2] *See* Pet. Br. 16-23; *Markman v. Westview Instruments, Inc.*, 116 S. Ct. 1384, 1396 (1996): "As we noted in *General Elec. Co.* v. *Wabash Appliance Corp.*, 304 U.S. 364, 369 (1938), '[t]he limits of a patent must be known for the protection of the patentee, the encouragement of the inventive genius of others and the assurance that the subject of the patent will be dedicated ultimately to the public.' Otherwise, a 'zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims would discourage invention only a little less than unequivocal foreclosure of the field,' *United Carbon Co.* v. *Binney & Smith Co.*, 317 U.S. 228, 236 (1942), and '[t]he public [would] be deprived of rights supposed to belong to it, without being clearly told what it

held out by the federal patent system [is] disclosure in exchange for exclusive use." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 159 (1989); *id.* at 149-51. Under this standard, determining the scope of the patent is a matter of reading and interpreting documents to discern what the patentee has asserted and what it has surrendered, a task that, when performed in infringement litigation, is well within the traditional function of judges. *See Markman*, 116 S. Ct. at 1395.

The Federal Circuit, in fundamental disagreement, held that the scope of the protected "invention" is not determined by interpreting the patentee's own statement of its invention. After such interpretation is exhausted, the inquiry—first undertaken by other inventors and market participants trying to avoid infringement, later undertaken by a finder of fact in adjudicating infringement—then proceeds to an independent assessment of the scientific facts to determine what changes from the patentee's asserted invention would make a "substantial difference." Under this standard, the invention awarded to the patentee is not limited to what the patentee has defined through the statutory PTO processes for issuing (or reissuing) patents, but instead is defined in court through factual determinations, even allowing recapture of coverage the patentee dropped in the PTO to obtain the patent, all based on a reassessment in the infringement action of what the patentee *could* have claimed. In the present case, the Federal Circuit applied its standard to hold that a patentee who has throughout its patent disclosed a chemical process with clearly stated limits (*e.g.*, a pH of approximately 6.0 or more), and included those limits at the unchallenged insistence of the PTO, nevertheless was entitled to a monopoly on a process that concededly falls outside any fair interpretation of those stated limits, even though the patent nowhere suggests that the repeatedly stated limits were unimportant to the process.

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is that limits these rights.' *Merrill* v. *Yeomans*, 94 U.S. 568, 573 (1877)."

The Federal Circuit's view should be rejected in favor of confining patent scope to what the patentee has *said* its invention is. The Federal Circuit's view does not follow from this Court's decision in *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605 (1950), or other precedents. It cannot be reconciled with the statute's fundamental requirement that patentees circumscribe their patent monopolies by the disclosures made to and approved by the PTO, so that other inventors, market competitors, and the public can understand with clarity and without costly independent experimentation where each such monopoly ends. And it would largely undo this Court's recent decision in *Markman*, where the Court insisted that the job of interpreting claim language be carried out so that " '[t]he limits of a patent [are] known,' " so that there is no " 'zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement,' " so that the public is " 'clearly told what it is that limits' " its rights. 116 S. Ct. at 1396. Those objectives would immediately be defeated by holding that the actual " 'limits of a patent' " protected in an infringement action extend beyond the interpretation of the patent's claims to an invention nowhere disclosed by the patentee but defined in litigation under an inherently uncertain "substantial differences" standard.[a]

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[a] Although Hilton Davis suggests otherwise (Resp. Br. 11), we do not understand this Court in *Markman* to have decided the issue presented in this case (which was already accepted for review, but not yet argued or fully briefed) by its passing quotation from a Federal Judicial Center publication that sketches the outlines of the lower court case law under review here. 116 S. Ct. at 1388 (" 'the heart of the invention' "). That reference formed no part of the rationale of *Markman*, which in fact strongly points the other way in its reaffirmation of the patent statute's condemnation of uncertainty about patent scope. Moreover, as Hilton Davis recognizes (Resp. Br. 24 n.24), this Court has broadly rejected the "heart of the invention" notion, specifically in the context of "combination" claims like the example cited by this Court (116 S. Ct. at 1388 n.1): "there is no legally recognizable or protected 'essential' element, 'gist' or 'heart' of the invention in a combination

1. *Facts.* Notwithstanding Hilton Davis's several attempts to relitigate the facts and to walk away from its earlier correct concession of no literal infringement (Resp. Br. 2-5 & n.4, 31 n.30), the facts of the case as it comes to this Court—found by the jury, amply supported by the evidence, and accepted by the courts below—are not properly in dispute. "Warner-Jenkinson's process operated at . . . a pH of 5." Pet. App. 4a.[4] Hilton Davis's patent claims expressly require a pH of at least "approximately 6.0." J.A. 36-37. Hilton Davis conceded below that the meaning of its claim words does *not* encompass Warner-Jenkinson's process: *e.g.*, the pH levels differ by a factor of 10, with the different acidity levels made possible by different chemical compositions of the dye solutions being filtered. The jury was not even presented with an issue of literal infringement. *See* Pet. Br. 4-5.

Hilton Davis added the pH limit to the originally submitted patent claims by amendment, at the specific behest of the PTO, so as to secure issuance of the patent. *See* Pet. Br. 3-4. And no lower pH level is asserted to be within the invention anywhere else in the lengthy description of the invention in the patent, which contains numerous references to pH levels, all at least 6. *See* Pet. Br. 5 n.6. Moreover, Hilton Davis's patentee gave testimony showing that this limit was no accident: when the claimed filtering process was applied to industrial-size volumes of the dye solution, lower pH levels would cause

patent." *Aro Mfg. Co., Inc. v. Convertible Top Replacement Co., Inc.*, 365 U.S. 336, 345 (1961). In any event, *Markman* says nothing about the *sources* for determining the scope of the invention: what the patentee has disclosed and what it has surrendered; or independent factual inquiry.

[4] Hilton Davis relies for a contrary assertion entirely on the testimony of a witness who said that, on a visit to Warner-Jenkinson's plant, he saw four filtering machines, one of which was not in operation, and one of the machines had a pH reading of 6. *See* Resp. Br. 4-5 n.4, ultimately relying on J.A. 121. The same witness, however, when asked if it was the machine that was shut down for cleaning (filled with cleaning solution rather than dye) that had a pH of 6, acknowledged: "Could have been." J.A. 122.

"tremendous foaming problems in the plant." J.A. 111. In short, the "invention" awarded to Hilton Davis in this suit—with infringement found without questioning Warner-Jenkinson's independent development of *its* process—was concededly one not asserted as the invention anywhere in the patent, and, indeed, one deliberately dropped during the application process in order to obtain the patent.[5]

2. *The Agency-Approved Patentee's Own Description of the Invention as Defining Patent Scope.* In our opening brief, we argued that the "invention" protected against infringement should reach no farther than what the patentee asserted as its invention through the prescribed PTO-approval processes, *i.e.*, no farther than the fair meaning of the patent claims plus substantive equivalents *disclosed as such* in the remainder of the patent (and its documented history). *See* Pet. Br. 38-41; *see also* Pet. Br. 34-37 (surrender as part of disclosure standard). We also argued that, if the Court were to reach the question whether patent scope should ever extend beyond the fair meaning of the patent *claims* (which it need not), the Patent Act would be best construed to preclude such an extension. Pet. Br. 41-49. In either event, we argued, the Federal Circuit's standard was deeply incompatible with the statutorily prescribed role of precise "claiming" of the boundary of the protected invention through prescribed agency processes. Pet. Br. 13-31.

a. Hilton Davis seeks to deny this basic incompatibility. Resp. Br. 18-19. But its denial is devoid of any explanation, relying instead only on its overreading of *Graver*. *Ibid.* The inconsistency, moreover, has been widely and repeatedly recognized precisely to the extent that, as Hilton Davis must positively insist, the Federal Circuit's doctrine of equivalents extends patent scope

[5] The jury rejected Hilton Davis's charge of willful infringement (J.A. 69), and the court of appeals accepted "Warner-Jenkinson's lack of intent" and "evidence of independent development" (Pet. App. 20a).

beyond where the claim's meaning leaves off. Resp. Br. 42-43.[6]

As a correct caution against crabbed *construction* of patentees' language, there is no such incompatibility. *See* 4 D. Chisum, *Patents* § 18.04[1][a][i], at 18-74 (1995) ("Viewed as an aid to claim construction, as a prescription against sterile literalism in construction and application of claim language, the doctrine of equivalents is fully consistent with the notion that the claim measures the scope of the patent monopoly."), quoted in part at Litton Br. 11. But once the doctrine is not "so limited," once the meaning of words is left behind for expansion of patent scope beyond those meanings, it is well recognized that "a tension exists between the doctrine and the fundamental notion that the claim measures the scope of the patent monopoly" (*id.* at 18-78). *See also id.* § 18.04, at 18-73 (doctrine is "contrary to the general principle that the claims measure the scope of the patent monopoly"); Pet. Br. 20-21, 43-45 (quoting numerous sources); *Claude Neon Lights, Inc. v. E. Machlett & Son*, 36 F.2d 574, 575 (2d Cir. 1929), *cert. denied*, 281 U.S. 741 (1930) (doctrine "anomalous" for this reason). And a similar tension obviously exists between a standard requiring independent experimentation and factual inquiry in court to determine the scope of the protected "invention" and the basic decision of the federal patent law, made toward the end of the Nineteenth Century, to shift onto the Patent Office and the patentee, and away from the courts and the public, the duty to define the protected

[6] Here, it was correctly conceded by Hilton Davis, and accepted below, that a pH of "approximately 6.0" cannot, as a matter of English-language and scientific meaning, encompass a pH of 5 (which is ten times as acidic). The *en banc* Federal Circuit, having reaffirmed in the *Markman* case that claims are to be given a fair construction in their full documentary context and held that this task was one for judges (*Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979-81 (1995), *aff'd*, 116 S. Ct. 1384 (1996)), held in this case that the determination of equivalents is—precisely because it involves going beyond the meaning of the words of claims—a quite different task, requiring a factual determination by juries.

invention. *Keystone Bridge Co. v. Phoenix Iron Co.*, 95 U.S. (5 Otto) 274, 278-79 (1877); *see* Pet. Br. 17.

b. Contrary to Hilton Davis's unelaborated assertion (Resp. Br. 21; *see also* U.S. Br. 27), the Federal Circuit's decision effectively circumvents the careful limits set by Congress in granting the PTO authority to reissue a patent with broadened claim language—authority restricted to making the new claim language reflect "the invention disclosed in the original patent" (35 U.S.C. § 251). This Court recognized in *Keystone* that expansion of patent scope beyond claim language was in reality a substitute for the reissue process. 95 U.S. at 278 ("If the patentees have not claimed the whole of their invention, and the omission has been the result of inadvertence, they should have sought to correct the error by a surrender of their patent and an application for a reissue."). Moreover, this Court's leading modern precedent on reissue confirms that the "invention" *is* limited to what the original patent asserted and is *not* to be determined by a later independent inquiry into whether scientific facts make the original disclosure unduly narrow.

In *U.S. Industrial Chemicals, Inc. v. Carbide & Carbon Chemicals Corp.*, 315 U.S. 668 (1942) (cited at Resp. Br. 45), this Court held that a reissued patent was invalid because it was not "for the same invention" (Rev. Stat. § 4916, predecessor of 35 U.S.C. § 251) as the original patent. The original patent claims *and specification* described a process in which the introduction of water was required, whereas the reissued claims treated the introduction of water as noncritical. 315 U.S. at 671-75. The Court held that the claims were not "for the same invention," based on its "comparison of the *disclosures* of the two instruments." 315 U.S. at 675, 671 (emphasis added). The Court explained that it was not enough that, as a matter of scientific fact, the change made no difference in substance: the "invention" was limited to what the initial patent clearly disclosed. *Id.* at 676-80.

The Court explained that the invention of the original patent was only what was "intended or sought to be

covered or secured by the original patent" and that "[t]he required intention does not appear if the additional matter covered by the claims of the reissue is not disclosed in the original patent." *Id.* at 676 (footnotes omitted). That the patentee knew more than it said was irrelevant:

> If there be failure of disclosure in the original patent of matter claimed in the reissue, it will not aid the patentee that the new matter covered by the reissue was within his knowledge when he applied for his original patent. And it is not enough that an invention might have been claimed in the original patent because it was suggested or indicated in the specification. It must appear from the face of the instrument that what is covered by the reissue was intended to have been covered and secured by the original.

Ibid. (footnotes omitted). Nor was it relevant that both lower courts, based on expert testimony, had found that the change in the process (omission of water) was "immaterial" (*id.* at 677), "not essential to the technological success of the process" (*id.* at 679), and that the patentee knew this "when he applied for his original patent." *Id.* at 677. "The inquiry at once arises, if this were so, why did he not say so." *Ibid.* The disclosure, rather than in-court scientific evidence, determines the "invention" protected by the patent: "It is inadmissible to enlarge the scope of the original patent by recourse to expert testimony to the effect that a process described and claimed in the reissue, different from that described and claimed in the original patent, is, because equally efficacious, in substance that claimed originally." *Id.* at 678 (footnote omitted).

The Federal Circuit's holding that the protected invention is to be scientifically defined in court cannot comfortably co-exist with *U.S. Industrial Chemicals.* That decision established—before the 1952 Act—that the "invention" protected by a patent claim is limited to what the patent on its face discloses as the invention, and the scientific immateriality of an element asserted to be part of the invention throughout the specification, even if that immateriality was known to the patentee, does not change

the protected invention to more than what was clearly disclosed. If courts are to look beyond the meaning of the patent claims, *U.S. Industrial Chemicals* makes clear that they may look no further than the full patent for what the patentee *said* its invention was.

c. Not surprisingly, Hilton Davis's efforts to point to supposedly contrary precedent fail. *See* Resp. Br. 30 n.29; *see also* Litton Br. 13. None of the cited precedents repudiates the central importance of disclosure, as recognized in *U.S. Industrial Chemicals.* Nor do any of the cited decisions contradict the necessarily implied requirement—which this Court has repeatedly stated—that any newly asserted equivalent must have been known to be so when the patent issued. *See* 4 D. Chisum, *Patents* § 18.04[3], at 18-17 to 18-125 (surveying Court's precedents stating this requirement; contrary rulings by the Federal Circuit, not this Court); Pet. App. 126-130a.

Limiting non-literal infringement to what is *disclosed* by the patentee serves fundamental patent policies. The core principle that patentees gain protection only for "*their* . . . Discoveries" (U.S. Const., Art. I, § 8, cl. 8)—for what *they* figured out that was "novel" and "non-obvious" (35 U.S.C. §§ 102, 103)—makes it difficult to encompass within the protected "invention" anything except what the patentee *knew* was equivalent to its claim. And the basic statutory bargain of "disclosure in exchange for exclusive use" (*Bonito Boats*, 489 U.S. at 159), together with the long-recognized compelling need for clear public notice of the scope of patents (*see* note 2, *supra*), justifies limiting the patentee's protected "invention" to what it disclosed as part of the invention, so that other inventors need not conduct independent experiments even to figure out the scope of the patentee's monopoly. Here, without such experiments, no one could have known whether, when industrial volumes of dye were used (*cf.* Resp. Br. 5 n.5, 34 n.24), the filtering process would function equivalently with a pH of less than approximately 6.0. In the absence of the rules that, in

Graver, restricted patentees' ability to write sufficiently protective claims (*see* Pet. Br. 33 n.26), patentees today are broadly able to make clear disclosures of their inventions. In these circumstances, if a patentee later asserts that the invention "really" encompasses more than was stated, "[t]he inquiry at once arises, if this were so, why did he not say so." *U.S. Industrial Chemicals*, 315 U.S. at 677.

d. One aspect of the principle that the patentee's protection is limited to what it asserted as its invention before the PTO is the long-recognized principle that a patentee may not recapture through the doctrine of equivalents what it provably dropped from its asserted coverage by narrowing amendments made at the insistence of the PTO, because such amendments constitute a surrender of coverage that makes clear what was *not* part of the asserted (and approved) invention. *See* Pet. Br. 34-37. The Federal Circuit rejected this limit, holding instead that a court in an infringement suit must independently reevaluate the reason for the documented surrender to decide whether the patentee actually *could* have secured approval for the patent without the dropping of coverage—even though the patentee did not pursue appeals from any rejections of coverage it believed erroneous. Hilton Davis briefly defends that ruling, but its defense plainly fails. Resp. Br. 33-34.

Hilton Davis relies entirely on two decisions of this Court as support for the Federal Circuit's rule (Resp. Br. 33, citing *Sutter v. Robinson*, 119 U.S. 530, 541 (1886), and *Exhibit Supply Co. v. Ace Patents Corp.*, 315 U.S. 126, 136-37 (1942)), but neither of the two decisions, nor any other decision of which we are aware, anywhere says that a documented dropping of coverage at the behest of the PTO is to be subjected to a judicial reevaluation in an infringement suit, so that such surrenders may be reversed if they were not after all legally required. This Court has in fact rejected such a judicial reexamination, stating that a patentee who is "dissatisfied with the rejection [of a broader claim by the PTO] . . .

should pursue his remedy by appeal; and where, in order to get his patent, he accepts one with a narrower claim, he is bound by it. Whether the examiner was right or wrong in rejecting the original claim, the court is not to inquire." *I.T.S. Rubber Co. v. Essex Rubber Co.*, 272 U.S. 429, 443 (1926) (citations omitted); *Smith v. Magic City Kennel Club*, 282 U.S. 784, 789-90 (1931). Core patent policies powerfully support this simple rule of surrender: the public must be able to rely on the documented record, and the patentee has ample means of self-protection, including rights of administrative and judicial appeal from improper rejections.[7]

3. *Graver*. Hilton Davis, like the Federal Circuit, relies heavily on the notion that the 1952 Patent Act incorporated a broad doctrine of equivalents based on *Graver*. Resp. Br. 11-15. But it has no convincing answer to our showing that *Graver* itself is consistent with the much narrower doctrine, based on a strict disclosure-

[7] The discussion of the issue by the United States, which omits any reference to this Court's precedents (U.S. 20-23), illustrates how uncertain patent boundaries would be if judicial reexamination of the reasons for undisputed, documented surrenders were permitted. The United States states initially that this doctrine of prosecution history estoppel "prevents a patentee from obtaining, through the doctrine of equivalents, protection that he could not have obtained, *or* that he refrained from obtaining, from the PTO at the time the patent was issued." U.S. Br. 20 (emphasis added). It then suggests, however, that a court in an infringement suit *may* allow equivalents protection for what a patentee demonstrably "refrained from obtaining" depending on the reason for the dropping of coverage before the PTO. But while the United States indicates that avoidance of prior art counts as a good enough reason to preclude equivalents protection, it is unclear about when an inadequate specification is a good enough reason. U.S. Br. 22-23 ("should not *necessarily* estop") (emphasis added). The United States does not seem to speak to the problem of *inoperativeness* of the "equivalent" process as a reason—a very different "enablement" problem from the problem of merely insufficient explanation. *See* 2 D. Chisum, *Patents* §§ 7.03[6], [7](c) (1995). The evidence in this case was that pH levels below 6.0 caused "tremendous foaming" problems that, as far as Hilton Davis was aware, made the filtration process unworkable for its industrial purposes.

in-the-patent standard, that we have suggested. Pet. Br. 31-34. For that reason, and because *Graver* must be read in light of the long line of decisions of this Court on the role of claims and what the "invention" is, including those noted above, *Graver* cannot support the conclusion that the 1952 Congress codified a doctrine of equivalents like that adopted by the Federal Circuit.[8]

Unsurprisingly, the other precedents to which Hilton Davis points are equally unsupportive of a broad, generally available doctrine expanding patent scope beyond claim language that is required to give clear public notice. *See* Resp. Br. 11, 22, 25; Litton Br. 9-10. The earlier decisions come from an era when, as this Court has recognized, the role of claims—and hence their drafting and interpretation—was critically different: they were not understood to *define* with precision the outer reaches of patent scope. *See Markman*, 116 S. Ct. at 1390.[9] The

[8] Although *Graver* stated memorably that "[o]utright and forthright duplication is a dull and very rare type of infringement" (339 U.S. at 607), we do not understand how the statement supports a broader standard of nonliteral infringement: a high rate of violation is usually not viewed as an indication of the success or appropriateness of a legal standard. In any event, today literal infringement cases are not rare—or, as far as we know, rarer than nonliteral infringement cases. Among the most recent cases see, *e.g.*, *PPG Industries, Inc. v. Guardian Industries Corp.*, 75 F.3d 1558 (Fed. Cir. 1996); *Laitram Corp. v. NEC Corp.*, 62 F.3d 1388 (Fed. Cir. 1995); and *Transmatic, Inc. v. Gulton Industries, Inc.*, 53 F.3d 1270 (Fed. Cir. 1995). Appellate judges would seem likely to see a disproportionately small share of cases of "outright and forthright" infringement, which are most likely not to be pursued to that advanced stage of litigation.

[9] The Court in *Markman* noted the evolving importance of patent "claims" in the Nineteenth Century: "Although, as one historian has observed, as early as 1850 'judges were . . . beginning to express more frequently the idea that in seeking to ascertain the invention "claimed" in a patent the inquiry should be limited to interpreting the summary, or "claim,"' '[t]he idea that the claim is just as important if not more important than the description and drawings did not develop until the Act of 1870 or thereabouts.'" 116 S. Ct. at 1390 (citations omitted). That change in role for claims makes

more recent decisions, including all those from the 20th Century, *rejected* infringement findings for the very reasons we have urged, or involved the question whether to *restrict* potentially broad claim language that often used phrases like "substantially as described" to refer to the narrower description found in the specification. In the latter cases, rather than invalidate the patent claim as insufficiently supported by the specification, this Court, as a matter of construction or otherwise, narrowed the patent's coverage based on the specification. *See, e.g.*, Koykka, *Infringement of Patents*, 42 F.R.D. 43, 59-63 (1967); Hantman, *Doctrine of Equivalents*, 70 J. Pat. & Trademark Off. Soc'y 511, 521-40 (1988); *id.* at 539 (discussing *Sanitary Refrigerator* specifically and noting breadth of claim language). That approach, whatever its current validity (Pet. Br. 45 n.31), preserves rather than defeats the ability of the public to rely on claim language as the clear outer boundary of forbidden territory and reinforces the central principle that patent scope is limited to the patentee's *disclosures* in the patent. In short, by the time of *Graver*, there was no modern precedent of the Court that would have demanded overruling in order for the Court finally to announce, based on the Court's numerous precedents on the monopoly-defining role of patent claims, that patent scope could not be expanded beyond the meaning of the claims. *See* Pet. Br. 43-45 (quoting articles from period). *Graver* is the only significant precedent, and it is consistent with our proposed disclosure standard.[10]

inapposite earlier authorities calling for in-court definition of inventions without restriction to a fair interpretation of the language of claims—language that was, in any event, comparatively uninformative until the latter 1800s. *See* Pet. Br. 15-16, 43-46.

[10] In the absence of any such express repudiation by this Court, there were of course some lower court precedents invoking the doctrine of equivalents to expand claims, but even those decisions were comparatively few in number and—unlike the Federal Circuit decision here—treated the doctrine as exceptional, not routinely available to go beyond claim language. *See* Swanson, *A Discussion*

Even if this Court were to consider whether patent scope should *ever* exceed the fair meaning of valid patent claims, as *Graver* held permissible, *Graver* is not sufficient to compel an affirmative answer. The statute enacted by the 1952 Congress textually and structurally implies a commitment to agency-approved claims as the outer limits of the protected invention; pertinent legislative history reflects no endorsement of *Graver* but suggests a deliberately narrow use of "equivalents," in a context of *interpreting* certain "functional" claim language (35 U.S.C. § 112 (paragraph 6)); and *Graver* was well understood to be anomalous in light of a long line of this Court's decisions on claims as the limit of protection. *See* Pet. Br. 13-31, 42-45. But even if the 1952 Act is not read as repudiating *Graver*'s recognition of patent-scope expansion beyond claim language, it certainly cannot be understood as codifying such a doctrine: at most, it left this judicially created doctrine in the hands of this Court for continued consideration of its coherence in the overall patent regime. Nothing about what Congress did in 1952, or since, deprives this Court of the freedom to abandon the doctrine if it turns out, as the Federal Circuit has now held, that the doctrine cannot be narrowly cabined so as to preserve the basic role of agency-approved disclosures in furnishing clear public notice of the scope of patent monopolies.[11]

4. *Policy.* The basic policy issue in this case is whether it is possible to institutionalize the sort of flexi-

of the Application of the Doctrine of Equivalents in the Graver v. Linde Case, 33 J. Pat. Off. Soc'y, 19, 31 (1951); R. Ellis, *Patent Claims* 11-12, 41-42, 59-60 (1949).

[11] Our opening brief noted some of the post-1952 enactments by Congress that reaffirm the need for clear public notice of what territory is covered by valid patents. Pet. Br. 23-24. Hilton Davis cites some post-1952 amendments to the Patent Act, including the addition of "offers to sell" to the infringement provision (Resp. Br. 15), but there is no suggestion—and we know of no evidence—that Congress ever considered what the protected "invention" is when enacting any such provisions.

bility as to patent scope adopted by the Federal Circuit to deal with individual instances of inadequate claim drafting—a "substantial differences" standard applied in litigation—without systemic undermining of the statutory recognition of the public's need for clear notice of patent boundaries, supplied through agency-approved, patentee-drafted disclosures. Hilton Davis has not remotely shown how to accomplish such a feat, much less how to do so consistent with the intrinsic need to ensure that patent protection does not *stifle* innovation.[12] Any such showing is all the less likely under the disclosure standard we have set forth, which looks beyond the language of claims themselves to see whether the patentee has clearly asserted equivalents of the claimed invention in the more expansive and less constraining sections of the patent. Ultimately, the systemic statutory commitment to known patent boundaries simply cannot survive any standard that would allow a pH of 5 to be found part of a patent that was deliberately limited throughout to pH levels of approximately 6.0 or more (for reasons that could not be determined without independent experimentation).

[12] The recently issued FTC Report, summarizing considerable literature and extensive public hearings, reiterated that overbroad patent scope can be the enemy of both competition *and* innovation and that there is no reasonable consensus on how much protection is too much, which may, in fact, vary from field to field. FTC, *Anticipating the 21st Century: Competition Policy in the New High-Tech, Global Marketplace* ch. 6, ch. 8 at 12-17 (May 1996). "'We often talk about how important patents are to promote innovation, because without patents, people don't appropriate the returns to their innovation activity . . . . On the other hand, some people jump from that to the conclusion that the broader the patent rights are, the better it is for innovation, and that isn't always correct, because we have an innovation system in which one innovation builds on another. If you get monopoly rights down at the bottom, you may stifle competition that uses those patents later on, and so . . . the breadth and utilization of patent rights can be used not only to stifle competition, but also have adverse effects in the long run on innovation. We have to strike a balance.'" *Id.* Ch. 6, at 6 (quoting Joseph Stiglitz, chairman of Council of Economic Advisers). *See also* Merges & Nelson, *On the Complex Economics of Patent Scope*, 90 Colum. L. Rev. 839 (1990).

Two *amicus* briefs defend the Federal Circuit's standard of nonliteral infringement by arguing that the standard is needed to ensure "proper" protection for biotechnology inventions. Chiron Br. 14-18; Biotech. Ind. Org. Br. 7-10. But it is hardly possible in this case to decide whether the asserted problem is even a legitimate problem, *i.e.*, whether biotechnology patents are narrower than they *should* be (so as to reward true invention that would not otherwise have been forthcoming, without stifling subsequent improvements that may be just as important); and whether biotechnology inventors who can describe their inventions well enough to say what is new and to "enable" others to make them in their full asserted scope (35 U.S.C. § 112 (paragraph 1)) nevertheless are unable to "claim" what they have invented to capture that scope.[18]

[18] There is considerable debate over the proper scope of patent protection in biotechnology: some commentators have suggested that overprotection has stifled important improvements. *See, e.g.*, FTC, *Anticipating the 21st Century*, ch. 6 at 3-4, ch. 8 at 13-14 (FTC Staff Report, May 1966); Slutsker & Churbuck, *Whose Invention Is It Anyway?*, Forbes, Aug. 19, 1991, at 114 ("Overly broad patents discourage innovation by making it hard for inventors to come along and make an idea even more useful. . . . In case after case, latecomers to the protein research lose their court challenges and walk away from their research."); Ko, *An Economic Analysis of Biotechnology Patent Protection*, 102 Yale L.J. 777, 779, 790 n.98 (1992) (research dropped and deterred).

The examples offered by *amici* raise obvious questions about whether a genuine problem exists, and suggest the importance of carefully attending to just what the patentee has discovered or invented when analyzing the asserted inadequacies of "claiming" practice. If the patentee's invention is an isolated protein, with the patentee having discovered the amino acid sequence, then the claim may state the amino acid sequence; and it is irrelevant that there is "redundancy" in the genetic code. *See* BIO Br. 8-9; Chiron Br. 15-16. If what the patentee has done is to identify and isolate a "particular gene," *i.e.*, one *special* "sequence of DNA that encodes for a particular protein" (Chiron Br. 15), then it is unclear why the patentee's monopoly should extend beyond that sequence. Similarly, it is not clear why a patent claim for one protein should be protected against a *different* protein—"later discovered" by someone else—simply because, unbeknownst to the patentee, it had "functionally identical biological properties" (Chiron Br. 18). *See* Ko,

What is possible to decide here is that, if the problems in this particular field are real, their solution lies elsewhere—other than in a generally applicable, broad doctrine of equivalents that undermines the need for clear notice of patent scope in all fields.

If distinctive statutory rules for biotechnology inventions are needed, Congress has shown itself more than able to write them, having repeatedly written special rules for plants (35 U.S.C. § 162 (softening Section 112 disclosure requirement); *see also* Plant Variety Protection Act, 7 U.S.C. § 2321 *et seq.*; *Asgrow Seed Co. v. Winterboer*, 115 S. Ct. 788 (1995)) as well as for modern biotechnology inventions (*e.g.*, 35 U.S.C. §§ 156(a)(5)(B) and 271(e); Biotechnological Process Patents, Pub. L. No. 104-41, 109 Stat. 351 (Nov. 1, 1995)). In any event, the scope of patentable inventions, the proper means of drafting patent claims, and other potentially distinctive problems in biotechnology are the subjects of continuing and active administrative and judicial attention; and flexibility of claiming in this area is anything but foreclosed. *See, e.g.*, 37 C.F.R. § 1.821 *et seq.*; PTO, *Manual of Patent Examining Procedure (MPEP)* § 2420 *et seq.* (6th ed. 1995); Seide & Szanto, *Drafting Claims for Biotechnology Inventions*, in Fifth Annual Patent Prosecution Workshop: Advanced Claim and Amendment Writing 357-492 (1995).[14] It is through

supra, at 785 ("[A] single amino acid change at a critical locus can dramatically alter the shape of the protein, nullifying the protein's original function or creating an entirely new function. Because this relationship between structure and function remains unpredictable, creating an improved second generation protein may be as daunting a task as producing the first generation recombinant protein."); 2 D. Chisum, *Patents* § 5.04[6], at 5-429, 5-430 & n.5.1 (1955) ("Because of the unpredictable nature of chemical reactions, a newly-synthesized compound may be very similar in structure to known and existing compounds and yet exhibit very different properties."; "Similar problems concerning the impact of unpredictability are encountered in the field of biotechnology.").

[14] An extensive review of biotechnology patent claims is contained in Seide & Szanto, *supra*, at 438-56. *See also Scripps Clinic*

continuation of that focused process—rather than an across-the-board doctrine of equivalents that may be *particularly* unsuited to biotechnology (*see* Ko, *supra*, at 791)—that issues about further flexibility or breadth in the definition of particular protected inventions should be resolved. The expert agency (and the courts on review) can thereby address the problems of the particular subject, judging with respect to any unique problems of biotechnology and for particular types of inventions (*e.g.*, a protein, an isolated gene sequence, a process) what language will simultaneously capture the patentee's contribution to technology and provide sufficient notice to other researchers of the scope of the territory monopolized by the patentee. Such targeted clarifications, moreover, establish settled and reliable understandings about how particular inventions may be patented. Those subject-specific, expert-based, and stabilizing means of defining "proper" patent protection in this area make reliance on any special problems in biotechnology insufficient to

& Research Fdn. v. Genentech, Inc., 927 F.2d 1565, 1572 (Fed. Cir. 1991) ("Open-ended claims are not inherently improper. . . . They may be supported if there is an inherent . . . upper limit and the specification enables one of skill in the art to approach that limit."); *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.*, 927 F.2d 1200, 1214 (Fed. Cir.), *cert. denied*, 502 U.S. 856 (1991) (court "do[es] not intend to imply that generic claims to genetic sequences cannot be valid where they are of a scope appropriate to the invention disclosed by an applicant"); *In re Deuel*, 51 F.3d 1552 (Fed. Cir. 1995); *In re Bell*, 991 F.2d 781 (Fed. Cir. 1993); *Genentech, Inc. v. Wellcome Fdn. Ltd.*, 29 F.3d 1555 (Fed. Cir. 1994); Sheiness, *Patenting Gene Sequences*, 78 J. Pat. & Trademark Off. Soc'y, 121, 123, 124 (1996) ("many patents have issued containing broad claims that encompassed variants and alleles").

The PTO has required standardized computerized submissions for biotechnology patents (37 C.F.R. § 1.821; *MPEP* § 2421 *et seq.*), for the same reason that it has made significant (statutorily mandated) efforts to ensure ease of access to patents through computerized and other search mechanisms (*see* 35 U.S.C. § 41(i); *MPEP* § 902 *et seq.*; PTO, *Setting the Course for Our Future* 26-27 (Fiscal Year 1995 Review)): recognition of the need of inventors and businesses to be able to determine with clarity the boundaries of forbidden territory before they expend potentially vast resources in their own efforts to innovate and to compete in the marketplace.

justify a universally available, inherently uncertain standard for in-court definition of all inventions through a broad doctrine of equivalents.[15]

The inescapable *addition* of substantial systemic uncertainty as to patent boundaries (*cf.* Chiron Br. 19-20 (noting claim construction not perfectly precise)) is not the only problem with Hilton Davis's policy argument for departing from the meaning of the patent disclosure, which rests ultimately on an appeal to fairness and the basic patent-law policy of providing an adequate reward for the patentee's contribution to knowledge. *See* Resp. Br. 27, 35. The argument also is one-sided and misstates the patent statute's policy. The patent scheme's fundamental judgment to accept present monopoly returns in exchange for promoting innovations that would not otherwise occur has no direct application in a case of independent (and simultaneous) development. W. Bowman, *Patents and Antitrust Law* 17 (1973) (if "a patent monopoly were granted for a product which would have been forthcoming anyway, then the restricted output caused by the patent monopoly leads to a net social loss to the community"). And Hilton Davis cannot simultaneously insist on a uniform patent scope and on departures from the patent disclosures based on fairness to patentees "who have failed to express their complete

[15] *Amici* appear to suggest that requiring care in claiming may overburden the PTO and delay issuance of biotechnology patents. Chiron Br. 8; BIO Br. 9-10. But the alternative is to impose on the marketplace and then the courts the burdens of clarifying the scope of patents issued with less care—patents that, in the meantime, also deter economically beneficial competition and improvements within the zone of uncertainty. As for concern about the application process eating up substantial portions of the new 20-year-from-filing term of patents (replacing the former 17-years-from-issuance term), most biotechnology patents seem to be issued only slightly more slowly than other patents, and in under three years, *see* Sheiness, *supra*, at 136-37); the term may be extended to account for successful appeals from adverse PTO decisions (35 U.S.C. § 154(b)); and special extensions are prescribed for certain biotechnology inventions (*id.* § 156). Of course, problems in term length can be addressed again, if necessary, by Congress.

meaning" (*Claude Neon Lights*, 36 F.2d at 576), for any invocation of fairness requires consideration of the defendant's equities as well: here, substantial investment to arrive independently at the process the plaintiff seeks to monopolize despite its omission from the patent. A uniform, known patent scope demands adherence to the patent's disclosures as the definition of the patent monopoly.

5. *Judge or Jury.* Hilton Davis's final argument is that juries rather than judges should apply the doctrine of equivalents. Resp. Br. 36-50. This argument, however, is completely dependent on this Court's accepting the generally applicable "substantial differences" standard of the Federal Circuit, which calls for what the patentee invented to be defined by scientific testimony about what was technologically important or unimportant to the invention. A standard that, in contrast, limits the "invention" to what the patentee *disclosed* is plainly a matter for application by judges, as the interpretation of patent documents is at the core of judges' traditional role and expertise. *See Markman*, 116 S. Ct. at 1395.

CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

H. BARTOW FARR, III
(Counsel of Record)
RICHARD G. TARANTO
FARR & TARANTO
2445 M Street, NW
Washington, DC 20037
(202) 775-0184

J. ROBERT CHAMBERS
KURT L. GROSSMAN
WOOD, HERRON & EVANS
2700 Carew Tower
Cincinnati, OH 45202

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